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Epidemiology of atopic dermatitis in Poland. Economedica AD

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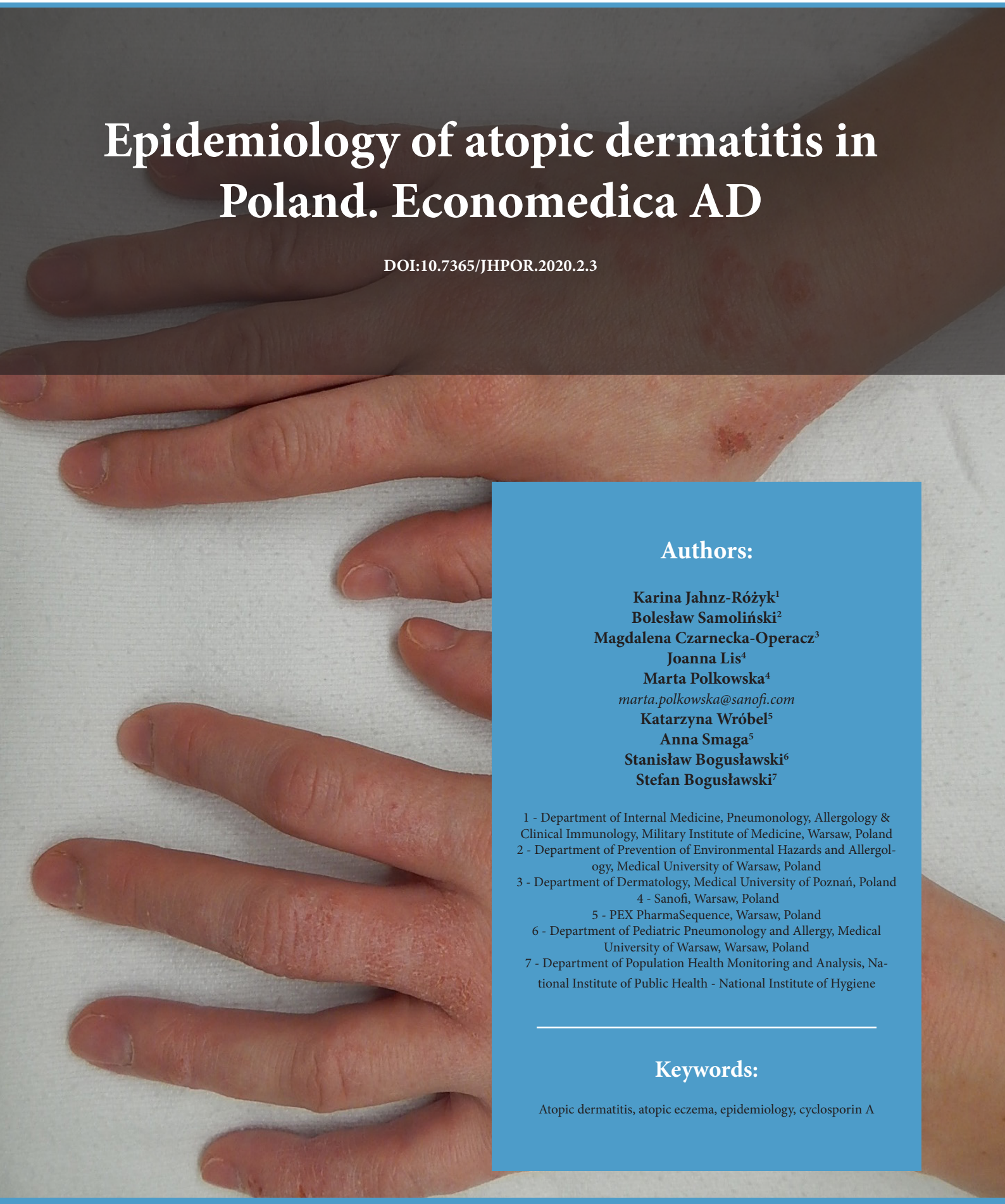

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Abstract

Introduction
Atopic dermatitis (AD) is a commonly diagnosed inflammatory disease of the skin, with a chronic and relapsing course, which clinically manifests itself through eczematous skin lesions. The diagnosis is mainly based on the clinical picture of the disease. The goal of this project was to quantify the total population of AD patients in Poland and to make an attempt to determine the clinical profile of the population of patients who are moderately or severely affected by the disease.

Methods
The Economedica AD project consisted of two parts. The core part of the study, carried out among a representative group of specialists in dermatology and venereology, concerned the information collected from these specialists regarding both the overall health condition of the AD patients, treated by these doctors, as well as the treatment methods used for adult patients with a severe or moderate course of the disease. The second part of the study was an omnibus study, carried out on a representative group of adult Poles, and it mainly included questions concerning the potential presence of clinical AD symptoms. The combination of the two research methods allowed for an extrapolation of the collected data onto the total Polish patient population and to present detailed characteristics of AD patients in Poland.

Results
On the basis of the omnibus study, the total number of adult AD patients in Poland was estimated to be 705,718 (2.24% of adult Poles). 178,234 adult patients (0.6%), who in the past 12 months experienced a severe or moderate exacerbation of clinical AD symptoms, are currently in the care of dermatologists. Study population, i.e. patients with moderate or severe exacerbation of clinical condition, was also analysed in terms of general course of the disease. As a result of the analysis, estimated number of patients with mild AD was 18,560 (10% of the surveyed population); those with moderate AD: 113,264 (64% of this population), whilst 46,410 (26%) had severe AD. It should be noted that the estimates excluded patients who had only mild disease symptoms in 12 months prior to the study. In the case of 20% of severe AD patients, systemic cyclosporine therapy was initiated within the 12 months prior to the study, while 26% of patients received it within the last 24 months. An analysis of EASI or SCORAD indexes, measured for these two patient groups after the end of cyclosporin therapy, demonstrated the inefficacy of treatment for 47% and 34% of the patients respectively. Despite the clinical indications for such treatment, 54% of the patients underwent systemic cyclosporin therapy in neither of the two analysed periods, mainly due to the patient's refusal (66%) or contraindications (24%) of the use of cyclosporine (according to the binding guidelines concerning cyclosporine therapy).

Conclusions
The prevalence of AD among Polish adults was estimated to be 2.24%. The results of the Economedica AD project with respect to the number of adult AD patients are similar to results of the studies carried out both in Poland and in other European countries.

A detailed analysis of the subgroup of patients with a severe course of atopic dermatitis has shown a high percentage of patients for whom cyclosporin therapy turned out to be either ineffective (in 47% and 34% of patients treated with CsA in 12 and 24 months prior to the study) or intolerable; this was due to the patient's refusal (about 66%) or contraindications connected with the patient's health status or comorbidities (24%).

Introduction

Atopic dermatitis (AD) is a common chronic and relapsing inflammatory dermatosis. It is currently estimated to affect 30 out of every 10,000 Poles. The highest prevalence of the disease is observed among children, yet it declines with age.[1] The pathophysiology of atopic dermatitis is complex and results from the co-existence of a wide range of genetic, immunological, and environmental factors. AD is characterised by a profound dysfunction of the epidermal barrier (both structural and functional), which causes, among other things, transepidermal water loss (TEWL). A chronic inflammation of the skin is an extremely important factor in the development of the disease process and course, which leads to changes in the expression of the genes associated with

the above disorders of the structure and function of the epidermal barrier. The consequence of these changes is, for example, damage of the epidermis as a barrier, thus facilitating the penetration of various extrinsic factors such as allergens or various irritants, toxins, etc.[2] The issue currently raised is also the role of abnormal skin microbiome in AD patients, which may influence the severity of the disease process.[3] The diagnosis of atopic dermatitis is predominantly based on characteristic clinical objective and subjective symptoms. Unfortunately, studies concerning AD-characteristic biomarkers, which would qualify patients for individual endotypes and phenotypes, have not been completed yet. Chemokine TSLP seems to be a very good candidate as an AD biomarker candidate, yet a group of at least 8 biomarkers, adequately characterised, is practically necessary to allow for acomplete diagnosis and further stratification of patients into individual types of the disease. AD is still the most often diagnosed with the use of the Hanifin and Rajka criteria; the most significant symptoms include itching, distinct morphology, and the location of skin lesions, as well as the chronic and relapsing character of the disease. A positive family or personal history of atopy is also relevant.[4] The severity of the disease is classified with scoring systems, among others, with the SCORAD index, which assesses the nature and intensity of individual skin lesions (typical of atopic eczema) and their extent.[5] An appropriate emollient therapy is certainly essential for the treatment of atopic dermatitis. According to the current guidelines, mild AD patients, during flare-ups, mainly receive local anti-inflammatory treatment: topical glucocorticosteroids or topical calcineurin inhibitors. In the case of both mild and moderate AD, the recommended therapeutic approach includes the so-called 'early intervention', which is based on the early initiation of topical glucocorticosteroids or calcineurin inhibitors (depending on the intensity of the skin inflammation) a pro-active maintenance therapy with topical tacrolimus preparations, which significantly reduces the occurrence of skin inflammation relapses i.e. the exacerbations of the disease process mentioned above. However, severe AD cases require immunosuppressive therapy – and, apart from systemic glucocorticosteroids (administered orally or intravenously in severe skin inflammation flare-ups and erythrodermic exacerbations) the AD patients mainly receive cyclosporin A as well as off-label mycophenolate mofetil, methotrexate or azathioprine. This treatment, however, in some cases, carries the risk of serious side effects,[6] which are certainly due to the drug action's characteristics. In most cases this does not pose a real threat to patients, especially when cyclosporine is taken into consideration. The treatment should be carried out with an appropriate dose, individually selected for each patient, and requires the monitoring of potential side effects, especially concerning kidney and liver function and increased arterial pressure. With regard to cyclosporin, it is also necessary to educate the patient on the possible occurrence of the so-called "rebound phenomenon", in cases when treatment is terminated too abruptly. Therefore, a gradual, slow reduction of the cyclosporine dose is necessary to maintain its actual clinical improvement effect.

The first biological drug, registered for the treatment of patients with a moderate and severe form of AD, is **dupilumab** – a monoclonal antibody against receptor subunit α of IL-4 and IL-13 receptors,[7] which has obtained breakthrough therapy status in this indication.[8] It is well known that atopic dermatitis does not lead to mortality, which is why it is often underestimated by physicians and healthcare decision-makers. It has, however, a significant impact on patients' lives. A large number of studies show a considerable reduction in the quality of life for AD patients.[9,10] AD symptoms have impact on sleep quality and can cause anxiety or depression in patients. In relation to the above observations, AD patients often have suicidal thoughts caused by such a drastic deterioration of their quality of life, which – unfortunately – sometimes lead to real suicide attempts. Many people believe the disease does not pose a threat to the patient's life, but the real picture is different; the disease often causes anxiety, depression, and suicidal thoughts mentioned above.[11] A major study carried out by Ring et al. has demonstrated that as many as 88% of AD patients report that the disease restricts their ability to "get on with life".[12] The results of the above studies show that the severity of the disease significantly influences patients' functioning in everyday life. Furthermore, a French study with about 1,000 patients has shown that AD involves additional cost, which increases together with the severity of the disease, amounting to as much as EUR 460 per year for severe AD patients.[13] It is also worth noting that AD is an independent risk factor for stroke and myocardial infarction, as well as the development of a wide range of different systemic autoimmune diseases; this risk also increases as the severity of the disease gets higher.[14]

The main objective of the Economedica AD project was to estimate the number of patients and to describe the population of adult patients in Poland who have experienced a moderate or severe exacerbation of AD symptoms and remain under the specialist care of dermatologists. The frequency of cyclosporin A (CsA) use was also studied in this group. An additional objective of the project was to determine the total number of patients suffering from atopic dermatitis in Poland.

Material and Methods

The Economedica AD project consisted of two studies, carried out simultaneously. The main part was a study conducted within a group of dermato-venereologists and concerned their own AD patients. In addition, a representative (in terms of age, gender, and place of residence) group of adult Poles participated in a population study, in which the respondents were selected in line with the omnibus methodology (Figure 1). Omnibus-type studies are cyclical surveys containing questions concerning many areas, with a goal of generating representative population samples. The data was collected from December 2017 to March 2018.

The main part of the Economedica AD project

This part of the project included a group of 95 specialists (dermato-venereologists), representative in terms of province, type of city (provincial cities and others), and type of practice, working in outpatient settings and their patients diagnosed with atopic dermatitis.

A two-stage sampling was used in this part.

Stage 1: random-quota selection of physicians

Physicians working in open care settings were invited to participate in the study. They were selected to ensure that the sample distribution reflected the distribution of specialist open-care clinics with an NFZ contract for services in the field of dermatology and venereology, across provinces and two types of cities: provincial and others. The sampling algorithm used for physicians was based on two steps. First, open-care clinics (where the recruitment for the study started) were randomly selected. Then, in the case of a refusal to participate in the study, a procedure based on the geographical proximity of subsequent clinics to the clinics chosen initially was used. The sample ensured a representation of dermatologists from hospital outpatient clinics and other specialist clinics, respectively 25 and 70. One physician per clinic participated in the study.

Stage 2: patients' selection

Each physician participating in the study kept a register of adult AD patients attending, specifying the occurrence of mild, moderate, and severe episodes of skin inflammation flare-ups in the last 12 months (Form A). Patients, who experienced a severe or moderate exacerbation of the disease process in the last 12 months and who required any type of treatment were qualified for a detailed description; this was done within Form B concerning their clinical condition and the form of treatment. The patients were qualified for the study in the order of follow-up visits at specialists.

The intensity of a clinical exacerbation of AD was subjectively assessed by the physicians participating in the study. The specific numbers of patients with severe or moderate AD described using Form B was imposed in advance so that both patient groups could be represented in the sample (respectively 50% of the sample, approximately 6-8 patients per specialist). In total, 700 patients were described in the study with the use of Form B (Table 1). The criterion for including a patient in the study was based on the intensity of clinical symptoms in the course of a single skin inflammation exacerbation registered in the last 12 months. Taking into account that a single flare-up of the disease does not define the actual severity of the disease, additional data was collected concerning the general course of the disease in Form B i.e. the physician's overall assessment whether the patient has a severe, moderate or mild form of the disease, regardless of the intensity of the flare-up episode selected for assessment, occurring in the last 12 months.

Form B contained the data concerning the treatment connected with the exacerbation of the disease process, based on which the patient was qualified for the study. Additionally, data was collected about the patient's qualification for systemic treatment and the type of systemic treatment covering the last 24 month period.

The omnibus study

The study was carried out on a group of adult Poles, representative in terms of gender, age (18-24, 25-34, 35-44, 55+) and the size of location (large/ medium/ small cities and villages). The objective of this part of the project was to estimate the incidence of AD symptoms in the adult population in Poland and to determine which rate of this

Table 1. Sample structure and population – Form B

MAIN PART OF THE PROJECT	Number of physicians and patients subject to a detailed description within Form B / TYPE OF CLINIC	A CLINIC	A HOSPITAL CLINIC	TOTAL
A MEDICAL DOCUMENTATION ANALYSIS	DERMATOLOGISTS participating in the study	70	25	95
	PATIENTS with a moderate AD flare-up in the last 12 months	254	97	351
	PATIENTS with a severe AD flare-up in the last 12 months	243	106	349
	In total, patients described in Form B	497	203	700

population was included in the main part of the project (carried out among physicians). The source of data was an on-line questionnaire including questions on the occurrence of AD symptoms in the last 12 months. These were defined in the questionnaire as an itchy rash inside the elbows and behind the knees, around the ankle joints, beneath the buttocks, around the neck, the ears or eyes; additionally there were questions as to whether the respondent was previously diagnosed with AD and physicians of which specialties they consulted with regard to their symptoms in the last year. In total, answers were obtained from 2,088 respondents.

Weighting and extrapolation

In order to determine the number of adult Polish patients with moderate or severe AD exacerbations who seek specialist advice from dermato-venereologists, and also in order to be able to make conclusions on the clinical condition of patients and the therapeutic process used for these patients, the data obtained from the research sample was weighted and extrapolated. The following data collected in the study was taken into account: the proportions of patients with a registered severe or moderate exacerbation in the patient's clinical condition during the course of AD, the seasonality of flare-ups, the frequency of visits with respect to a specific patient, information on whether patients are in the care of one or more specialists, dermato-venereologists, the differences in the number of patients in the care of individual specialists participating in the study. The calculations also took into account the total number of dermato-venereologists in Poland and the number of adult Poles, estimated by the Central Statistics Office (GUS) at 31,537,200 in 2016.

The data collected during the study originated from medical documentation or a patient interview. No additional diagnostic or therapeutic interventions were performed during the study, nor were there any additional specialist consultations.

The analysis was carried out by PEX PharmaSequence, the calculations were made using SPSS 20.0 software.

Results

Out of all the patients included in the omnibus study, 193 declared an occurrence of AD symptoms or symptoms typical of AD within the last 12 months, including 42% who visited a physician in relation to these symptoms and 32% who visited a dermatologist. On the basis of the omnibus study and the study with physicians, the total number of adult AD patients in Poland was estimated to be 705,718, which accounts for 2.24% of adult Poles. According to the Econemedica AD project, 178,234 patients, (0.06% of adult Poles) for whom in the last 12 months an AD exacerbation of a severe or moderate clinical character was registered, are in the care of dermatologists (Table 2). However, taking into account the overall course of the disease, 70 out of 700 patients described in the main part of the project (carried out with specialists) were diagnosed with mild, 366 with moderate, and 264 with a severe clinical course of atopic dermatitis. Having

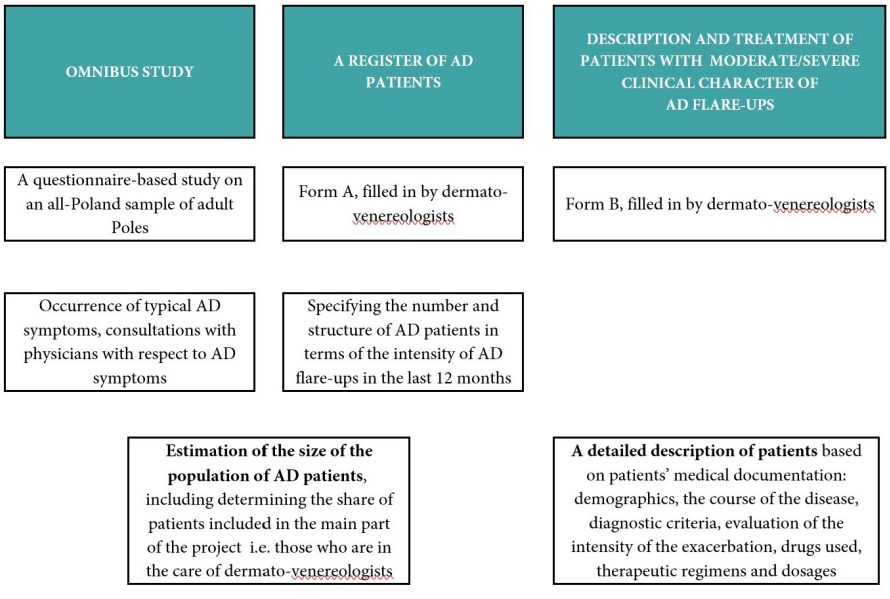

Figure 1. Structure of the Econemedica AD project

extrapolated this data to the Poland-wide level, the number of patients, under the specialist care of dermato-venereologists, with a mild course of AD was estimated at 18,560 (10% of the surveyed population), with moderate at 113,264 (64%), and with severe at 46,410 (26%). These results concern the population included in the detailed description by specialists, i.e. patients who experienced a moderate or severe exacerbation of the disease; it did not take into account patients who only had mild clinical AD symptoms in the last 12 months.

The analysis of the correlation between the severity of the disease process and the clinical profile of AD symptom exacerbations has shown that among patients with moderate AD flare-ups in the last 12 months, 14% were patients with a mild course of the disease, 86% – patients with a moderately intensified course of the disease, and 1% – patients with a severe clinical course of AD. Among patients with severe skin inflammation flare-ups in the last 12 months, 5% were patients with a mild course of the disease, 27% – with a moderate course, and 69% – with a severe course of atopic dermatitis (Figure 2).

Since the intensity of a single exacerbation does not define the overall clinical course of AD, further analyses focused on the course of the disease process, which seems to provide a more detailed and credible picture of the long-term character of the disease in terms of its severity for individual patients.

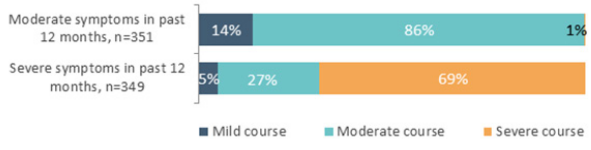

Figure 2. Correlation between the clinical profile of AD and the intensity of AD symptom flare-ups registered in the last 12 months

One of the analysed elements of the adopted systemic treatment was the use of oral cyclosporin A for patients with a severe course of the disease. Patients, for whom CsA was used in the preceding 12 months accounted for 20% of this patient group. In the case of 38% of them, the therapy was discontinued; for 47% of them clinical ineffectiveness was observed. In the longer term covering the last 24 months, the percentage of those for whom oral CsA therapy was used amounted to 26%. The drug was discontinued for almost 60% of them, including 34% for whom it failed to deliver therapeutic effects. Treatment efficacy was evaluated by the physicians using the two scoring systems that are most often used for clinical evaluation of AD patients in research projects – EASI and SCORAD. At the end of the cyclosporin therapy, treatment efficacy was evaluated for 58% and 47% of patients respectively, undergoing treatment within 12 and 24 months prior to the study (Table 3).

Among patients with a severe course of AD for whom CsA was not used during the preceding 12 and 24 months, in 46% of them the physician did not find indications to initiate systemic immunosuppressive therapy. The reasons for not using oral CsA as a therapy of choice for severe AD patients were also analysed. Most frequently it resulted from the patients' refusal of such treatment; respectively 66% and 67% in groups where such therapy was not used in the last 12 months and in the last 24 months. Other reasons included: planned pregnancy (ca. 5%), comorbidities (ca. 20%) or the patient's overall health (ca. 10%). 13% of the patients for whom CsA was not used in either of the two periods covered by the study, had contraindications for the use of the drug (Table 4).

Discussion

The projection of the results of the study on commonly diagnosed AD suggests that approximately 700,000 adult Poles suffer from this dermatosis, with the prevalence of

Table 2. Population of the specific patient subgroups, as specified in the study

Subgroup:		Share in the surveyed population	Share in the all-Poland adult population*	Population: projection to the all-Poland level	Unweighted population ascertained in the study
Population of patients included in the study: Adult patients with severe or moderate EXACERBATIONS OF AD SYMPTOMS in the last 12 months, remaining under the specialist care of dermato-venereologists		100%	0.6%	178,234	700
THE COURSE OF AD, according to the physicians, adult patients under specialist dermatological care	severe	26%	0.15%	46,410	264
	moderate	64%	0.36%	113,264	366
	mild	10%	0.06%	18,560	70

* The number of adult Poles in 2016 by the Central Statistics Office (GUS): 31,537,200

the disease in Poland amounting to ca. 2.24%. The prevalence of atopic dermatitis varies greatly across individual countries. This is certainly affected by the environment, socioeconomic conditions, the availability of health services and drugs (including the aspect of the reimbursement of therapeutic preparations and their price), as well as significant genetic factors. In Eastern Europe, China, and Central Asia the prevalence AD is lower than in other regions.[15] In a questionnaire-based study carried out in various European countries, which included ca. 80,000 people in total, the occurrence of AD clinical symptoms was declared by 2.3% of the respondents.[16] In an analysis involving over 110,000 patients with metabolic syndrome, based on the data obtained from medical documentation, AD was diagnosed in the case of 2.7% of the patients.[17] Another study concerning the prevalence of AD in various countries across the world has shown that in the European Union, the highest prevalence is recorded in Italy and amounts to 8.1%, while in Spain it is 7.2%, in Germany – 2.2%, and in the USA and Canada – 4.9% and 3.5% respectively.[18] Certainly, significant differences across specific studies may be influenced by both the sources of data as well as the methods used for the analysis; hence the credible comparison of individual studies is impossible without a detailed analysis of the methodology applied in each case. In the last quarter of a century several attempts were made to determine the prevalence of AD in Poland. In a study carried out on a group of approximately 1,500 respondents in the Łódź Province in the late 1990s, the prevalence of AD was rated at 0.9%.[19] The PMSEAD study, carried out in a similar time period on a group of less than 13,000 Polish females and males, showed that the disease affected 1.6% of them.[20] The above studies were based on questionnaire surveys completed by patients. In the ECAP study, carried out in 2006-2008 on a group of over 9,000 persons aged 20-44, 3% had clinical symptoms of atopic dermatitis. In the analysis, both the physicians' answers and the data collected in questionnaires with patients were taken into account.[21] At the same time, the study by Raciborski et al. was based on data obtained from the National Health Fund. The population affected by AD was estimated on the basis of the health services provided within the National Health Fund (NFZ) in 2008-2017. The study included patients, for whom the physicians used the appropriate ICD-10 disease identification code. On that basis the prevalence of AD in Poland was estimated at 0.3% of the total population, without the division into children and adults.[1]

The Economedica AD project, the results of which are described in this article, is the first ever published study where the obtained results are extrapolated onto the total population of adults in Poland. In the previously mentioned questionnaire studies,[15-21] the percentages of AD patients in the surveyed populations are similar. The significantly lower prevalence in the study by Raciborski et al. may result from the inappropriate or incomplete use of the ICD-10 code by the physicians. In Poland, the choice of the ICD-10 code often depends on the level of financing provided by the NFZ. The choice of the ICD-10 code by a physician is also influenced by the presence of comorbidities experienced by the patient. For this reason data provided by NFZ is often incomplete and unfortunately lacks credibility. According to the authors of this paper, the number of AD patients may also be underestimated because of the use of privately financed visits, which are not included in the analysis.[1] This results from difficulties in accessing allergy specialists and dermatologists in Poland within the public healthcare system financed by the NFZ. It constitutes an extremely important methodological difference between the two research projects; in the Economedica AD project, presented by us, the data concerning the population of AD patients treated in Poland also came from private healthcare settings. The project has shown that the group which most frequently seeks and requires specialist help are patients with the most severe form of the disease and such patients are more often described by physicians in the study and registered in the NFZ database. On the basis of the data collected from the specialists and dermato-venereologists, patients with a severe and moderate course of AD accounted for approximately 0.5% of the Polish adult population which is close to the results of the study by Raciborski et al. It also seems that the number of patients with a mild course of AD is underestimated, since only patients remaining under the specialist care of dermato-venereologists are included in the analysis. This is clearly seen when comparing the results of the omnibus study and the physicians' reports. While in the omnibus study the prevalence of AD was 2.24%, it was 0.57% based on the physicians' reports. The majority of the patients registered by the dermatologists were patients with moderate or severe AD – 0.51%. This shows that the number of patients with a mild course of AD can be underestimated if this research method is used. The data from the previously quoted systemic review seems to confirm this, as a mild clinical form of AD accounted for 50-85% of the cases in the analysed studies.[13] The significant difference in the prevalence of AD between questionnaire-based studies and physicians' reports may also result from the fact that patients with mild AD require specialist help less often.

Patients with a severe clinical course of AD account for 0.15% of the population of adult Poles. For comparison, in the analysis covering three areas of Spain, severe AD was diagnosed in 0.08% of patients. More than 46% of them were treated with cyclosporin.[22] In this study (Economedica AD), the group of patients treated with this drug made up 20% and 26% for 12 and 24 months respectively. In the case of a significant percentage of the patients the therapy was discontinued (38% and 60%) due to the lack of efficacy being recorded using EASI or SCORAD (47%

Table 3. Characteristics and clinical effect of the CsA therapy carried out in the population of AD patients with a severe clinical course of the disease		
PATIENTS WITH A SEVERE FORM OF AD as assessed by the specialist, dermato-venereologist		
INEFFECTIVE ORAL CsA THERAPY		
Total number of patients/ population of AD patients with a severe disease process	46,410	
	↓	↓
Oral CsA was administered:	in the last 12 months	in the last 24 months
Patients who underwent CsA*	9,314 (20%) ↓	11,840 (26%) ↓
CsA discontinued from the systemic therapy for AD patients	3,582 (38%) ↓	7,046 (60%) ↓
Population of patients where the clinical condition after CsA discontinuation of their systemic therapy was assessed (EASI and SCORAD)	2,094 (58%) ↓	3,284 (47%) ↓
Lack of efficacy (EASI≥20 or SCORAD>50)	1,666(80%)(47%)	2,390 (73%)(34%)

*number and percentage relating to the level indicated with the arrow

Table 4: Patients with severe AD where cyclosporin was not used		
PATIENTS WITH A SEVERE FORM OF AD as assessed by the physician		
PATIENTS WHO DID NOT USE CSA		
Total number of patients	46,410	
	↓	↓
Absence of cyclosporin in the treatment:	within the last 12 months	within the last 24 months
CsA not administered	37,097 (80%) ↓	34,570 (74%) ↓
–due to the absence of indications for CsA	17,019 (46%)	15,994 (46%)
–another reason, otherwise the patient would be eligible for CsA	20,078 (54%)	18,576 (54%)
The reason for not using CsA despite indications:		
1. Patient's refusal	13,309 (66%)	12,516 (67%)
2. Planned pregnancy	1,039 (5%)	1,039 (6%)
3. Comorbidities/related treatment	3,731 (19%)	3,731 (20%)
4. Patient's overall health	2,061 (10%)	2,061 (11%)
5. Other (contraindications/overall health)	399 (2%)	194 (1%)
Patients with contraindications for CsA * (at least one of 3, 4, 5)	4,747 (24%) (13% for whom CsA was not administered)	4,543 (24%) (13% for whom CsA was not administered)

and 34%). These percentages are significantly higher than in the 10-year observational studies on AD patients in the Netherlands, where the inefficacy of CsA was at 15%.[6] At the same time they are closer to the results of other, open, randomised studies concerning the optimal CsA dosage in patients with a severe course of AD, where the efficacy of the drug was between 59.8%-51.7% depending on the dosage.[23] However, in the Economedica AD project the evaluation of therapy efficacy was often not objective. In the group of patients who took CsA within the 2 years prior to the study, SCORAD or EASI were only measured for 47% of the patients. In the case of many patients, the decision to modify therapy was based on the supervising physician's subjective assessment, with no measurement using the afore-named scoring systems. For more than 50% of patients, cyclosporin was not initiated despite the existing indications, which most frequently – in the case of 66-67% of the patients – resulted from the lack of the patient's consent to therapy. This shows a considerable fear of the initiation of such therapy which may be connected with the frequent side effects of cyclosporin.[24] Therefore, clear communication with patients with a severe clinical form of AD is extremely important.

Both parts of the project had their limitations. In the part carried out with dermatologists, the limitation lies frequently in the subjective assessment of the severity of the disease, unfortunately without the use of the existing scoring systems for objective assessment of the clinical condition of an AD patient. On the other hand, in the omnibus study, the AD diagnosis was not verified by a physician.

Summary

The objective of the Economedica AD project was to reflect the actual clinical situation of the population of AD patients with severe or moderate exacerbations of clinical symptoms, who remain under specialist dermatological care in Poland. In particular, we wanted to obtain credible data on both the AD-related condition of patients and the therapies used for these patients. This unique, two-element methodology enabled us to perform detailed analyses relating to treatment in various, narrow subgroups of patients under specialist dermatological care, including – which is extremely relevant – patients with a severe clinical course of AD.

At the same time, the data obtained from the omnibus study provided us with a complete picture of various aspects connected with AD epidemiology in Poland, taking into account patients whose treatment and monitoring are carried out without the involvement of specialist healthcare. The study has demonstrated the occurrence of AD symptoms in adult patients at a level of 2.24%, which is consistent with the previously quoted epidemiological studies.

The analysis of patients' treatment in the last 12 months has shown that 20% of patients with a severe clinical form of AD are treated with oral cyclosporine A. For many of these patients, the therapy was discontinued and the assessment using EASI SCORAD indicated its inefficacy (in the case of 47% of those whose CsA therapy was discontinued).

80% of patients with a severe clinical form of AD did not undergo oral systemic CsA therapy, although approximately half of them met the eligibility criteria for this therapy. In 2/3 of the cases the reason for not using CsA was the patient's refusal, while in 1/4 of the cases there were contraindications for the use of CsA connected with the patient's overall health condition or comorbidities. In particular, it is the population of patients with a severe form of AD that definitely needs novel therapeutic solutions which should be implemented as soon as possible; a delay in the use of more appropriate therapies for severe forms of AD can lead to significant impact to quality of life and co-morbid conditions such as sleep disorders, anxiety and depression.

Authors declare none potential conflicts of interest.

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